

Food and Drug Administration Rockville MD 20857

INAD 010697 P 0030 and T 0031

David A. Erdahl
 National INAD Coordinator
 USFWS, National INAD Office
 Bozeman Fish Technology Center
 4050 Bridger Canyon Rd.
 Bozeman, MT 59715

AUG 7 2003

Dear Dr. Erdahl:

We refer to your submission dated February 5, 2003, as amended February 10, 2003, to your investigational new animal drug (INAD) file for Aquaflor[®] (florfenicol). You requested review of a study conducted to demonstrate the effectiveness of florfenicol medicated-feed to control mortality in fingerling cutthroat trout, *Oncorhynchus clarki*, due to coldwater disease caused by *Flavobacterium psychrophilum*.

Based on the information in this submission and the information contained in INAD 010697, the Division of Therapeutic Drugs for Food Animals considers the EFFECTIVENESS technical section complete for the purpose of recommending approval of a New Animal Drug Application for the use of Aquaflor[®] (florfenicol) administered as a medicated-feed at a dose of 10 mg/kg of fish/day for 10 consecutive days to control mortality in freshwater-raised salmonids due to coldwater disease caused by Flavobacterium psychrophilum.

A final decision on the approval of the application will be made when all of the data for all technical sections are viewed as a whole and it is determined that:

- 1) the information contained in and referenced by the application supports approval;
- 2) the GMP status of each manufacturing facility is current and satisfactory;
- 3) if a claim for categorical exclusion was made, conditions for the categorical exclusion are still applicable.
- 4) there is no new information that would preclude the approval of the application.

This study as well as the studies included in submissions dated September 9, 2002, and January 7, 2003, should be included in the Freedom of Information Summary.

Future correspondence regarding your submission to the INAD file should include the date of this letter and our file number, INAD 010697 P 0030. A copy of this technical section complete letter should be included in the Administrative NADA.

If you need further information regarding this letter, please contact Dr. Donald Prater, Leader, Aquaculture Drugs Team, who may be reached at 301-827-7567.

Sincerely yours,

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Joan C. Gotthardt, D.V.M.
Director, Division of Therapeutic Drugs for
Food Animals
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